UNITED STATES DISTRICT COURT
SOUTHERN DISTRICT OF NEW YORK

IN RE: FOSAMAX PRODUCTS LIABILITY LITIGATION	MDL No. 1789 1:06-md-1789 (JFK)
This Document Relates to: All actions	**MEMORANDUM OPINION & ORDER**

JOHN F. KEENAN, United States District Judge:

Before the Court is plaintiffs' motion to compel the production of documents pursuant to Rule 26 of the Federal Rules of Civil Procedure. The gravamen of this motion is defendant Merck's refusal to produce certain materials predating 2003. The Court finds that the pre-2003 materials are relevant to plaintiffs' claims and must be produced, with certain significant restrictions that are detailed below. Plaintiffs' motion is granted in part.

BACKGROUND

This multidistrict litigation ("MDL") now includes over 550 actions. Plaintiffs claim that their ingestion of Fosamax caused them to develop osteonecrosis of the jaw ("ONJ") and other jaw-related injuries. Fosamax is an oral bisphosphonate used to treat osteoporosis and other bone disorders. It was approved by the United States Food and Drug Administration ("FDA") on September 29, 1995, was first sold shortly thereafter, and has been on the market ever since. Reports of an association between ONJ and intravenously

administered bisphosphonates first appeared in the U.S. published medical literature in September of 2003. An association between ONJ and oral bisphosphonates such as Fosamax was published the following spring. In July of 2005, Merck at the behest of the FDA added a "precaution" to Fosamax's label stating that ONJ has been reported in patients undergoing bisphosphonate therapy.

Plaintiffs used Fosamax at various times and for various durations throughout this span of years. Their complaints assert multiple causes of action against Merck, including strict liability for design defect and failure to warn, negligence and breach of warranty. To prevail on some of their claims, plaintiffs will have to prove, among other things, that Merck knew or should have known of a risk of ONJ before Fosamax allegedly caused their injuries, and that Merck failed to properly design and test Fosamax or warn of its risks.

Pursuant to Case Management Order ("CMO") No. 3, discovery in this MDL is currently scheduled to be completed on the last day of this year. CMO No. 3. ¶ 10. Fact discovery in the twenty-five potential early trial cases is scheduled to end on August 1, 2008, less than two months away. CMO 10 ¶ 5 (entered Jan. 31, 2007). These deadlines will be extended by two months, as stated in the final paragraph below, in light of this order compelling Merck to produce additional documents.

The Court has already reviewed discovery in this case that was submitted last year in connection with plaintiffs' unsuccessful motions for class certification. See In re Fosamax Prods. Liab. Litig., 248 F.R.D. 349 n.1 (S.D.N.Y. Jan. 3, 2008). Included within this were the affidavit and deposition testimony of plaintiffs' expert, Dr. Marx, who opined that a patient's risk of developing ONJ is "small" or "insignificant" until she has used Fosamax continuously for three years. Id. at 394, 397 n.9.

Plaintiffs served their First Request for Production of Documents on November 21, 2006. Merck served its objections and responses to the requests on January 22, 2007. (Decl. of David J Heubeck, Exh. 1 (Def.'s Objections and Responses to Plaintiff's First Request for Productions of Documents)). Merck objected generally to producing "any documents or information relating to FOSAMAX® prior to September 2003, the date when osteonecrosis of the jaw was first reported in the literature as occurring in temporal association with bisphosphonates." Id. at ¶ 4. Excepted from this date limitation were the official Investigational New Drug ("IND") and New Drug Application ("NDA") files, which Merck produced without any date limitation. These files contain documents relating to Merck's communications with the FDA about the development, approval, and post-marketing surveillance of Fosamax. They account for 856,992 of the

roughly 1.4 million pages produced by Merck so far. (Def.'s Mem. at 7-8.) Besides these materials, Merck has also produced other categories of documents without any date limitation.[1]

In a letter dated March 1, 2007, plaintiffs challenged Merck's objections to their discovery requests, including its objection to producing documents predating September 2003. (Decl. of David Heubeck Exh. 2 (Mar. 1, 2007 Letter from the PSC to David Heubeck and William Beausoleil)). The parties met and conferred in New York on March 8, 2007. Merck then sent a letter dated April 27, 2007 addressing the discovery issues raised at the conference. (Id., Exh. 3 (Apr. 27, 2007 Letter from David Heubeck to James F. Green and Shelley Sanford)). The letter stated that ONJ first surfaced in temporal association with Fosamax in 2003 and that Merck would produce certain categories of documents only back to the beginning of that year. Plaintiffs did not file this motion until April 18, 2008, almost a year later, claiming that discovery negotiations have finally reached an impasse. (Pls.' Mem. at 5).

[1] These categories of documents are the following: IND/NDA-related internal correspondence (109 pages); Adverse Experience Review Team ("AERT") minutes (49 pages); Periodic Safety Update Reports ("PSURS") (26,634 pages); Fosamax Project Team and Product Development Team Meeting Minutes (6,992 pages); Background documentation from ONJ worldwide event ("WAES") reports (1,817 pages); and the custodial files of six Merck scientists who had responsibility for Fosamax-related post-marketing surveillance, pre-clinical and clinical research and trial, and FDA submissions and communications (approx. 418,000 pages). (Def.'s Mem. at 7-8.)

1. The 2003 Date Limitation

Merck has imposed the 2003 date limitation on the following categories of documents: Field Sales Bulletins; Responses to Physician Information Requests ("PIRs"); Sales Training Materials; Labeling Meeting Minutes; Board of Director Meeting Minutes; correspondence with the FDA's Division of Drug Marketing, Advertising, and Communications ("DDMAC"); files from the Osteoporosis Marketing Team ("OMT") and its predecessor groups, and Sales Representative Discovery. Merck's rationale for withholding these pre-2003 materials is based on the fact that bisphosphonate-associated ONJ was not reported in the published medical literature until that year. Merck asserts that it could not have known of any association between ONJ and Fosamax before the first published reports, and that this is confirmed by the hundreds of thousands of pre-2003 documents that it has already produced. (Def.'s Mem. at 2, 13-14, 15-16.) Therefore, Merck contends, the pre-2003 documents are not relevant to plaintiffs' claims. In addition, Merck claims that the expense of collecting, reviewing and producing the pre-2003 documents would outweigh its likely benefit. (Id. at 2, 17, 19.)

Plaintiffs contend that the 2003 date limitation is unreasonable. They assert that cases of bisphosphonate-associated ONJ existed prior to 2003 and that this association could have been known or reasonably knowable to Merck before

then. (Pls.' Mem. at 1, 8-9; Pls.' Reply Mem. at 3-4.) Also, they maintain that their injury claims are not limited to ONJ but encompass other jaw-related injuries. (Pls.' Mem. at 1, 8-9.) Therefore, the requested documents are relevant and should be produced from the date Fosamax was first developed or, at the latest, 1995 — the year of Fosamax's FDA-approval and market release.[2]

a. Field Sales Bulletins

According to plaintiffs, field sales bulletins were used by Merck to disseminate new information, marketing instructions and promotional tools regarding Fosamax to Merck's sales representatives. Such information includes "obstacle handlers," which are scripted answers that a sales representative would provide in response to a physician's questions and concerns. Plaintiffs claim that these bulletins may contain communications about a potential relationship between Fosamax therapy and ONJ or other jaw conditions. This

[2] As revealed at oral argument, the appropriate end date for production is also subject to some ambiguity. In this motion, plaintiffs seek discovery of the requested documents until the "present date." In their First Request for Production, however, they sought these documents only up to November 21, 2006, the end date of the so-called "relevant period" for production. At oral argument, plaintiffs asserted that Merck should continue to produce documents within these categories as they come into Merck's possession, pointing out that Merck has produced other types of documents in such manner. In its opposition to this motion, Merck has sought to impose an end date limitation on two categories of documents discussed below-certain responses to Physician Information Requests and sales representative materials. Merck has not opposed producing the other categories of documents sought by plaintiffs up to the present date.

would be relevant to their claims of failure to warn and design defect, according to plaintiffs, because it could show that Merck had notice of a risk and instructed its sales representatives to understate it. (Pls.' Mem. at 11-12.)

Merck has produced field sale bulletins created after 2003, totaling 3,508 pages, but objects to producing any bulletins created before this date on grounds of irrelevance and burdensomeness, described above. (Def.'s Mem. at 7, 16-17.)

b. Responses to PIRs

Plaintiffs have requested information that Merck provided in response to all inquiries about Fosamax from physicians. These documents are referred to as "concepts" or responses to "Physician Information Requests" ("PIRs"). Plaintiffs state that responses to PIRs "typically may contain summaries of both published and unpublished clinical trial data, comparisons to other drugs, discussions of medical literature, and/or product labeling." (Pls.' Mem. at 12.) Plaintiffs believe that the PIRs might contain admissions by Merck or concerns raised by Merck's employees or physicians about ONJ or jaw-related issues.

Merck has produced all PIRs created after 2003, totaling 28,555 pages. Merck has also agreed to produce any responses to PIRs sent to a plaintiff's prescribing physician, even those sent before 2003, but only up until six months after

that plaintiff's last Fosamax prescription. However, Merck objects to producing all pre-2003 responses to PIRs, or responses sent to a plaintiffs' prescribing physician more than six months after that plaintiffs' last Fosamax prescription. (Def.'s Mem. at 17 & n. 18.)

c. Sales Training Materials

Plaintiffs have requested that Merck produce all sales representative training materials. These include both training materials relating specifically to Fosamax and those relating generally to sales representatives' interactions with physicians. Plaintiffs assert that instructions given by Merck to its sales representatives regarding their communication with physicians, contained in these training materials, are "highly relevant to issues of notice, fraud, and failure to warn." (Pls.' Mem. at 14.)

Merck has already produced the Fosamax-specific training materials currently in use (1,157 pages), along with others created after 2003 (1,641 pages). (Def.'s Mem. at 7.) In addition, it has agreed to soon produce generic training materials created after 2003. However, Merck objects to turning over any Fosamax-specific or generic training materials predating 2003.

d. Materials Related to Fosamax Labeling

Plaintiffs have requested any summaries or minutes of internal meetings at which Fosamax labeling was discussed. They contend that these materials "may contain admissions and/or provide insight into the dialogue between Merck and regulatory agencies relating to the safety and efficacy disclosures for Fosamax. Further, this material may indicate whether Merck or regulatory agencies, independent of any scientific literature, had safety concerns about Fosamax or bisphosphonates generally prior to 2003." (Pls.' Mem. at 15.) Merck has produced minutes from meetings of three internal committees dating back to 2003, totaling 134 pages, but objects to producing minutes created before then.

There are a few other disputed issues regarding labeling-related materials. First, plaintiffs contend that Merck will only produce materials that specifically reference ONJ. (Pls.' Mem. at 21.) Plaintiffs argue that all labeling materials should be produced without restriction, because they may contain admissions about the safety and efficacy of Fosamax, which they contend would be relevant to issues of fraud, causation, and failure to warn. (Id. at 21-22.) Plaintiffs also complain that limiting production to labeling materials that reference ONJ would exclude those referencing precursor symptoms

for ONJ and other jaw-related injuries alleged by plaintiffs. (Id. at 22)

Merck contends that the pre-2003 labeling materials have nothing to do with the jaw-related issues in this case, which surfaced "circa 2005 and thereafter." (Def.'s Mem. at 18.) It points out that it has already produced labeling materials, including draft and final labels, that were submitted to the FDA as part of the NDA. (Id.) In addition, plaintiffs have received the custodial files of Merck employees who, according to Merck, would have been involved in labeling issues. (Id.) Merck claims (as it did in its April 27, 2007 letter) that it would be too burdensome to locate and produce label drafts not contained in the NDA and custodial files because Merck does not maintain a separate file for draft labeling. (Id.)

Plaintiffs respond that, if Merck considered label drafts containing different risk information than the drafts ultimately submitted to the FDA for approval, this would be relevant to plaintiffs' failure to warn and fraudulent marketing claims. (Pls.' Reply Mem. at 6-7.) Plaintiffs request that the Court order Merck to identify employees involved in Fosamax labeling and search their custodial files for the materials at issue. (Id.)

Finally, Plaintiffs also complain that Merck has objected to producing materials relating to Merck's overseas regulatory activities, including foreign labeling and animal or lab testing or analysis. (Pls.' Mem. at 22; Def.'s Mem. at 18-19.) Merck has produced the custodial files of the two employees primarily responsible for international regulatory issues regarding Fosamax from 2003- May 2006. At oral argument, Merck stated that collecting, translating and producing the regulatory documents submitted in the many countries around the world where Fosamax is sold would be highly burdensome. Plaintiffs responded that they would be willing to forego their request for foreign labeling materials, provided that Merck produce any "causality assessments" and source documentation related to Fosamax adverse event reports of ONJ or other jaw-related injuries that were reported in other countries.

e. Board of Director Meeting Minutes

Plaintiffs also seek the minutes of all Board of Director meetings at which Fosamax was discussed, asserting that "executive decisions relating to the development, testing, and marketing of Fosamax are highly relevant to [their] claims." (Pls.' Mem. at 15.) Merck has produced only the minutes generated after 2003, totaling 61 pages. Merck refuses to produce any minutes created before 2003, claiming that, even though Fosamax was discussed at those meetings, the minutes

"have almost nothing to do with Plaintiffs' claims." (Def.'s Mem. at 19.)

f. DDMAC Correspondence

Plaintiffs have requested Merck's correspondence with the FDA's Division of Drug Marketing, Advertising, and Communications ("DDMAC"). They assert that the DDMAC has cited Merck for engaging in misleading promotions of Fosamax in the past, pointing to four letters from the DDMAC that Merck received between 1997 and 2001, none of which involved ONJ or jaw-related injuries. (Pls.' Mem. at 15; Pls. Reply Mem. at 5 n.1.) Plaintiffs assert that "[t]he extent to which Merck has demonstrated a pattern and practice of misleading physicians about the safety and efficacy of Fosamax is critical to the claims and defenses asserted in this litigation. (Pls.' Mem. at 15-16.) Merck has produced 514 pages of DDMAC correspondence going back to 2003. Merck claims, again, that it could not have known of a potential ONJ association before 2003, therefore it could not have been cited by the DDMAC for misleading physicians about such an association before then. (Def.'s Mem. at 19.)

g. Files of OMT and predecessor groups

Plaintiffs assert that materials from the osteoporosis marketing team ("OMT") and predecessor groups will reflect "Merck's marketing strategies, programs, and concerns relating to Fosamax" and are highly relevant to their claims. (Pls.' Mem.

at 16.) Merck has produced 40,552 pages of these materials going back to 2003. Merck claims that its marketing personnel could not have contemplated a risk of ONJ at a time when Merck's scientists were unaware of it. (Def.'s Mem. at 20.) It also states that producing these materials from the time of Fosamax's development would yield an additional 160,000 pages, given the very broad search terms used to identify responsive documents. (Id.)

h. Sales Representative Discovery

Plaintiffs initially requested the custodial files of all Merck sales representatives who called on plaintiffs' prescribing physicians or their offices in the twenty-five potential early trial cases. (Pls.' Mem. at 16-17.) The parties have reached an agreement in principle to narrow this request, but once again disagree on the appropriate date limitation.

Under the agreement, Merck will not produce the entire custodial files of all sales representatives who called upon plaintiffs' prescribing physicians. Instead, Merck will initially produce the call details, call notes, call topics, customer beliefs, responses to questions and "My Call" presentations associated with sales representatives who called

on the physicians.[3] The call and belief notes contain details of communications between sales representatives and physicians. They are stored in an electronic database called FACTS. In addition, Merck will produce materials reflecting Merck's communications with prescribing physicians from eleven other electronic databases identified in Merck's memorandum. (Def.'s Mem. at 20-21). After reviewing these materials, each plaintiff in the twenty-five potential early trial cases would select four sales representatives who called on their prescribing physician. Merck would make full personnel and custodial file productions for the four selected representatives. Plaintiffs then would select two of the four representatives for depositions.

Merck objects to producing any sales representative materials that predate 2003. In addition, Merck intends to cut off production of these materials at a date six months following a given plaintiffs' last prescription for Fosamax. (Def.'s Mem. at 22.)

Plaintiffs contend that the pre-2003 materials are relevant because they will contain Merck's safety and efficacy

[3] Merck has objected to producing materials for sales representatives who merely called the offices of the prescribing physicians but not the prescribing physicians themselves. (Def.'s Mem. at 22.) Although plaintiffs initially requested these materials, they have not pressed for them in this motion.

disclosures to its sales representatives; documents concerning a given physician's prescribing habits; Merck's marketing strategies and relationship with that physician; and any concerns raised by the physicians about Fosamax. (Pls.' Mem. at 17-18.) They claim that many of these materials exist in an easily-searchable electronic format, and that Merck has admitted to having begun collecting and reviewing these materials. (Id. at 19.) Plaintiffs also challenge Merck's decision to cut off production at a date six months after each plaintiff's last prescription for Fosamax. (Id. at 18-19; Pls.' Reply Mem. at 8-9). They assert that Merck's more recent communications with prescribing physicians "may support or contradict the parties' claims related to causation, notice, and failure to warn, and/or may bear on the bias or credibility of the physicians at issue." (Pls.' Reply Mem. at 8-9.) Also, some plaintiffs were not diagnosed with ONJ until after six months following their last Fosamax prescription. Plaintiffs maintain that, in such cases, the six month limitation would deny plaintiffs access to information during the critical period in which they informed their physicians that they had ONJ. (Id. at 9.)

2. Other Issues

Apart from the 2003 date limitation issue, the parties dispute the extent of Merck's discovery obligations with respect to two categories of documents:

a. Source Materials Underlying Adverse Event Reports

Plaintiffs have requested production of Adverse Event Reports ("AERs") for Fosamax. They have also requested the source documentation underlying AERs in which ONJ or jaw-related injuries were reported. Merck has produced source documentation for reports of ONJ, but has not produced documentation for reports of jaw-related injuries. (Pls.' Mem. at 21; First Decl. of Jeffrey Grand, Exh. S (Mar. 31, 2008 email from David J. Heubeck)).

Plaintiffs contend that source documentation for all events involving jaw-related injuries is important because ONJ cases were likely underreported during clinical trials and post-marketing surveillance, for several reasons. First, they claim that there was no reporting code for ONJ during Fosamax's clinical trials and so it may have been reported inconsistently. (Pls.' Mem at 21; First Decl. of Jeffrey Grand, Exh. T (Mar. 28, 2008 Dep. Tr. of Anastasia Daifotis, M.D.)). Second, they assert that Merck's analysis of its clinical trials for the incidence of ONJ excluded events not requiring hospitalization, thereby overlooking cases of ONJ or jaw-related injuries diagnosed and treated in an outpatient environment. (Id.) Plaintiffs also claim that bisphosphonate-associated ONJ was not widely understood by physicians who prescribed Fosamax and participated in clinical trials. (Id.) Plaintiffs wish to

review the underlying source documentation for reports of jaw-related injuries to evaluate whether the adverse events reported were correctly diagnosed by the reporting physician or by Merck. (Id. at 20.)

Merck objects to this request on the ground of burdensomeness. Merck claims that the request, if granted, would require it to collect, review and produce hundreds of thousands, if not millions, of pages associated with the thousands of adverse events reported in the more than twelve years that Fosamax has been on the market.[4] This would be an unnecessary burden, Merck contends, because plaintiffs themselves can locate the information they seek. The Periodic Safety Update Reports ("PSURs"), already produced, provide line-item descriptions of all adverse events reported since 1995. Each line item is associated with a unique Worldwide Adverse Experience System ("WAES") number. Merck suggests that plaintiffs should identify from the PSURs the ONJ or jaw-related events for which they desire the underlying source documentation and provide Merck with the corresponding WAES numbers. Merck will then trace the WAES number to whatever source materials exist for those adverse events and produce those materials. (Def's Mem. at 23-24.)

[4] This claim is exaggerated because, as plaintiffs clarify in their reply memorandum, they only seek documentation for AERs reporting ONJ or jaw-related injuries. (Pls. Reply Mem. at 9.)

Merck also points out that, in its April 27, 2007 letter, it offered to search the WAES database as well as the clinical trial database to identify relevant adverse events and underlying information, using search terms that plaintiffs could suggest. (Id. at 24; Decl. of David Heubeck, Exh. 3 ¶ 25 (Apr. 27, 2007 Letter from David Heubeck to James F. Green and Shelley Sanford)). Merck states that plaintiffs neither responded to this offer nor suggested search terms, but instead waited a year and filed this motion to compel.

Plaintiffs reply that Merck has already searched the WAES database with relevant search terms in an internal study undertaken by Merck to determine the incidence of ONJ among bisphosphonate users. (Pls.' Reply Mem. at 10.) According to the study, Merck identified a certain number of "well-documented" and "suspected" reports of ONJ between July 1993 and December 2006. (Id.; Second Decl. of Jeffrey Grand, Exh. 11.) At oral argument, plaintiffs also pointed to a 2004 FDA post-marketing safety review which found 12 reported cases of ONJ associated with Fosamax use between September 1995 and 2004. Plaintiffs seek the source material for all reports of ONJ and jaw-related adverse events so that they can conduct a similar review using their own experts. At a minimum, plaintiffs contend, Merck should produce the source documentation for the

reports that Merck identified in its internal study. (Pls.' Reply Mem. at 10.)

b. IMS Physician Level Data

Plaintiffs initially requested data regarding the Fosamax prescribing history of plaintiffs' prescribing and treating physicians. This data is maintained by IMS, a third party vendor to Merck and other pharmaceutical companies. Plaintiffs contend that changes in a physician's prescribing habits in response to changing marketing and risk information available for Fosamax is relevant to plaintiffs' failure to warn claims. (Pls.' Mem. at 24.)

Merck objects only to providing IMS data for plaintiffs' treating physicians, and does not object to producing such data for prescribing physicians. (Def.'s Mem. at 24-25.) In their reply memorandum, Plaintiffs state that they are willing to accept IMS data for prescribing physicians only (and not treating physicians), if (1) such data can be shown to the prescribing physician at deposition or trial;[5] and (2) Merck agrees to produce IMS data for treating physicians if Merck has

[5] Plaintiffs complain in their memoranda that Merck has conditioned producing IMS data for prescribing physicians on plaintiffs' promise not to show that data to the prescribing physicians during deposition or trial. However, Merck does not mention any such condition in its memorandum.

evidence that such physician also prescribed Fosamax or other bisphosphonate therapies. (Pls.' Reply Mem. at 11.)

Extended oral argument on the motion to compel was heard on June 2, 2008, and I reserved decision.

APPLICABLE LAW

Rule 26(b)(1) of the Federal Rules of Civil Procedure provides in part that "[p]arties may obtain discovery regarding any non-privileged matter that is relevant to any party's claim or defense." Relevance is defined broadly under Rule 26(b)(1): "Relevant information need not be admissible at the trial if the discovery appears reasonably calculated to lead to the discovery of admissible evidence." The term "reasonably calculated" means "any possibility" that the information sought may be relevant. See Daval Steel Products, a Div. of Francosteel Corp. v. M/V Fakredine, 951 F.2d 1357 (2d Cir. 1991) (citing Morse/Diesel, Inc. v. Fidelity and Deposit Co. of Maryland, 122 F.R.D. 447, 449 (S.D.N.Y. 1988)). Where relevance is in doubt, the district court should be permissive. In re Honeywell Int'l, Inc. Sec. Litig., 230 F.R.D. 293, 301 (S.D.N.Y. 2003).

Despite the liberal construction afforded the federal discovery rules, "Rule 26 vests the trial judge with broad discretion to tailor discovery narrowly and to dictate the sequence of discovery." Crawford-El v. Britton, 523 U.S. 574,

598 (1998). Subsection (b)(2)(c) requires a court to deny discovery of even relevant material if it finds that:

> (i) the discovery sought is unreasonably cumulative or duplicative, or can be obtained from some other source that is more convenient, less burdensome, or less expensive; (ii) the party seeking discovery has had ample opportunity to obtain the information by discovery in the action; or (iii) the burden or expense of the proposed discovery outweighs its likely benefit, considering the needs of the case, the amount in controversy, the parties' resources, the importance of the issues at stake in the action, and the importance of the discovery in resolving the issues.

Fed. R. Ci. P. 26(b)(c)(2). In addition, the Court has authority to shift some of the expense of discovery to the party seeking it. See See Oppenheimer Fund, Inc. v. Sanders, 437 U.S. 340, 358 (1978) (stating in dicta that a district court has discretion to condition discovery on the requesting party's payment of costs); 8 Charles Alan Wright, Arthur R. Miller & Richard L. Marcus, FEDERAL PRACTICE AND PROCEDURE § 2008.1. It is clear that the court's role at the discovery stage is largely discretionary.

DISCUSSION

1. The Requested Pre-2003 Materials Are Relevant

The association between bisphosphonate therapy and ONJ may have been known or reasonably knowable to Merck before it was first reported in the published medical literature in September 2003. Merck is in frequent communication with prescribing physicians about their patients' experiences with Fosamax. It was reported in the media that Novartis

Pharmaceuticals Corporation, defendant in the In re Aredia and Zometa Products Liability Litigation, MDL No. 1760, received notice from a doctor of a potential association between its IV-bisphosphonate drugs and ONJ well before the September 2003 report was published. Geeta Anand, Jaw Ailment Shows Industry Moves Slowly on Drug Warnings, Wall St. J., Dec. 8, 2004, at B1 (stating that Dr. Ruggiero claimed to have informed Novartis of a potential ONJ-association in 2001, and that Novartis officials claimed to have first heard from him in July 2002). Similarly, Merck may have received notice of a potential ONJ-association from doctors before 2003. Merck's assertion that it could not have possibly known of any association before it was first reported in the published literature is questionable.

Many plaintiffs have alleged that their injuries stem at least in part from their pre-2003 use of Fosamax. What Merck knew or reasonably should have known about an association between Fosamax and ONJ or jaw-related injuries before that year is directly relevant to plaintiffs' strict liability and negligence claims. Each of the categories of documents requested "appears reasonably calculated" to produce evidence of Merck's knowledge. If doctors had contacted Merck before 2003 to inquire about a potential ONJ association, Merck may have sent PIR responses to those doctors. Merck also might have created field sales bulletins and training materials instructing

its sales representatives on how to handle such inquiries. Merck also may have discussed them at internal meetings and possibly even addressed them tentatively in drafts of labels ultimately not submitted to the FDA. By the same token, Merck very well may have received no notice and taken none of these actions. But even the absence of such evidence would be relevant to plaintiffs' claims and Merck's defenses.[6] Although some of these scenarios may be speculative, the requested documents are relevant and discoverable under Rule 26(b)(1). That is the nature of discovery in American Federal civil litigation.

In addition, Merck's decision to cut off production of certain PIR responses and sales representative materials at a date six months following a given plaintiff's last prescription of Fosamax is unjustified. Merck's communications with a plaintiff's physician, either before or after the plaintiff used Fosamax, may contain evidence of notice or causation that is relevant to that plaintiff's case or the cases of other plaintiffs. Finally, Merck has not challenged the relevance of source documentation for AERs relating to ONJ and jaw-related injuries or of IMS data for prescribing physicians. These

[6] It also may be the case that such evidence of knowledge or notice, if it exists, would be in the pre-2003 scientific materials that Merck already has produced. However, this cannot be determined with such certainty to justify denying the relevant documents sought on the ground of cumulativeness.

materials are also discoverable, with certain restrictions detailed below.

Merck argues that plaintiffs must show good cause in order to obtain the requested discovery, for two reasons. The first one is based on the 2000 amendments to Rule 26(b)(1). Prior to those amendments, the rule permitted a party to obtain discovery of anything relevant "to the subject matter involved in the pending action." In 2000, the rule was changed to permit discovery of anything relevant to "any party's claims or defenses," narrowing the scope of material that is discoverable as of right. Under the amended Rule 26(b)(1), if a party seeks discovery of material that is merely relevant to the subject matter of the action, but not to any party's claim or defense, the court may order discovery for good cause shown. See 2000 Adv. Comm. Notes to F.R.C.P. 26(b)(1). Merck claims that materials pre-dating 2003 are not relevant to any claim or defense in this MDL, but merely to its subject matter. See Def.'s Mem. at 8-10. This argument fails because, as discussed above, the pre-2003 materials sought are relevant to plaintiffs' claims. Rule 26 does not require plaintiffs to show good cause.

Merck also asserts that, because this motion to compel was filed so late, it is tantamount to a request to amend the fast-approaching discovery deadlines. The disruption caused by this motion, although primarily attributable to plaintiffs'

unreasonable delay, arguably is attributable in part to Merck's refusal to produce relevant material.

2. Plaintiff's Requests Will Be Restricted

Although Merck must produce the pre-2003 materials, the production will be subject to several limitations. An overarching reason for limitation is plaintiffs' delay in bringing this issue to the Court's attention. Plaintiffs learned of Merck's intended date limitation in January 2007. Merck reaffirmed its position in its April 27, 2007 letter. Plaintiffs nevertheless waited until April 18, 2008, about a year later and less than four months before the scheduled conclusion of fact discovery in the early trial pool cases, to file this motion. Some restrictions appear necessary to keep proceedings in this MDL moving apace.

First, the date limitation imposed on each category of discovery (unless otherwise specified below) will be November 1, 1998, which is roughly the three-year anniversary of Fosamax's market release. Plaintiff's expert Dr. Marx has affirmed that the risk of ONJ from Fosamax is "insignificant" until three years of use. This does not rule out the possibility of a case of ONJ occurring after a shorter duration of Fosamax use. But it does make it very unlikely that Merck received any notice of a risk of ONJ from physicians, or discussed any such risk internally, before that time. The

benefit of going further back would be outweighed by the burden. This is especially so in light of the fact that plaintiffs have pointed to little from the copious pre-2003 materials already produced suggesting that bisphosphonate-associated ONJ was known or reasonably knowable to Merck before that time.

Second, plaintiffs will shoulder some of the expense of this additional production by paying Merck ten cents per page of electronic or hard copy document produced in compliance with this order. The aggregate cost to plaintiffs is to be capped at $150,000. The Court recognizes that most of the expense of this additional discovery, in the hours spent collecting and reviewing documents, will still fall on Merck. Shifting some of the cost is intended to create an incentive for plaintiffs to narrow their requests to focus on the documents they really want.[7] Within thirty days after the end of the first bellwether trial, Merck shall provide plaintiffs with an account of the pages produced in compliance with this order, broken down by document category. The PSC shall pay Merck the amount owed within thirty days, and shall apportion the cost among

[7] The ten cents per page figure is not intended to approximate Merck's actual costs of production. While plaintiffs argue that Merck incurs little cost reproducing documents already stored in electronic form, Merck estimates that the cost of reviewing these documents is over two dollars per page. All production other than that ordered compelled herein remains governed by the terms of CMO 13, which the parties stipulated to last year when Merck withdrew its motion for cost-shifting.

plaintiffs on a per plaintiff basis. Any dispute about the amount owed or the apportionment among plaintiffs shall be brought before Magistrate Judge Francis.

In addition, Merck's production of the pre-2003 materials, along with its production of source materials for AERs and IMS physician level data, will be subject to certain category-specific limitations, described below.

3. What Merck Must Produce

a. Field sales bulletins relating to Fosamax created between November 1, 1998 and the date of this order.

b. Responses to all PIRs for Fosamax sent between November 1, 1998 and the date of this order.

c. All Fosamax-specific and generic sales training materials created between November 1, 1998 and the date of this order.

d. From the date Fosamax was first developed until the date of this order: (1) all summaries or minutes of internal meetings at which Fosamax labeling was discussed; and (2) all draft labeling referencing ONJ or jaw-related injuries, provided that such drafts (a) are not contained in the NDA and custodial files already produced; and (b) can be located by Merck after a reasonably diligent search. Merck shall provide plaintiffs with a description of the efforts it intends to undertake to locate the labeling drafts.

Merck need not produce foreign labeling materials, but must produce any "causality assessments" and source documentation that relate to foreign AERS of ONJ or osteomyelitis, dated from November 1, 1998 to the date of this order.

e. Minutes for board of director meetings at which Fosamax was discussed, created between November 1, 1998 and the date of this order.

f. DDMAC correspondence relating to Fosamax dated from November 1, 1998 to the date of this order.

g. Materials relating to the Osteoporosis Marketing Team and its predecessors, created between November 1, 1998 and the date of this order. The parties shall try in good faith to agree on a narrower set of search terms to be employed in searching for these materials.

h. Sales Representative Materials: From the FACTS database, all call details, call notes, call topics, customer beliefs, responses to questions and "My Call" presentations associated with all of the sales representatives who called on the prescribing physicians of plaintiff in the early trial pool cases, created between November 1, 1998 (if available) and the date of this order. Merck shall also produce, for the same time period, sales representative discovery from the other electronic databases identified on pages 20-21 of its memorandum. Merck need not produce discovery for sales representatives who called the offices of plaintiffs' prescribing physicians but not the physicians themselves.

After reviewing these materials, each plaintiff will select four sales representatives and Merck will make full personnel and custodial file productions for those representatives. Plaintiffs then may select two of the four representatives for depositions.

i. Source Materials Underlying Adverse Event Reports: Merck shall produce the source documentation for the "well documented" and "suspected" reports of ONJ that Merck identified in the internal study that plaintiffs filed as exhibit 11 to Jeffrey Grand's second declaration. If plaintiffs wish to receive the source materials for any other AERs (other than those covered by subsection (d) above), they must identify the events from the PSURs and provide Merck with the corresponding WAES numbers by July 25, 2008. Merck shall promptly produce any source materials relating to the events so identified by plaintiffs. The November 1, 1998 date limitation shall not apply to this category of documents.

j. IMS Physician Level Data: Merck must produce IMS data for all prescribing physicians, but need not produce IMS data for physicians who treated but did not prescribe Fosamax to plaintiffs. Plaintiffs may show the IMS data to prescribing physicians at deposition or trial. The November 1, 1998 date limitation shall not apply to this category of documents.

CONCLUSION

Plaintiffs' motion to compel is granted in part. The deadline for the completion of all discovery in this MDL, set forth in paragraph 10 of CMO 3, is changed to March 2, 2009. The deadline to complete fact discovery in the potential early trial cases, set forth in paragraph 5 of CMO 10 (entered Jan. 31, 2007), is changed to October 1, 2008. The parties shall contact Judge Francis to schedule a discovery status conference within sixty days of this order and every sixty days thereafter.

SO ORDERED.

Dated: New York, New York
June 5, 2008

JOHN F. KEENAN
United States District Judge